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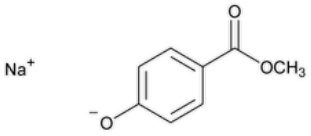
Methylparaben Sodium



$C_8H_7NaO_3$ 174.13

Benzoic acid, 4-hydroxy-, methyl ester, sodium salt;

Methyl *p*-hydroxybenzoate, sodium salt;

Sodium 4-methoxycarbonylphenolate CAS RN®: 5026-62-0.

DEFINITION

Methylparaben Sodium contains NLT 95.0% and NMT 102.0% of methylparaben sodium ($C_8H_7NaO_3$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.**

Standard: 0.5 g of USP Methylparaben RS

Sample: 0.5 g

Analysis: Dissolve the *Sample* in 5 mL of water. Acidify with hydrochloric acid, and filter the resulting precipitate. Wash the precipitate with water, and dry it over silica gel for 5 h. Repeat with the *Standard*.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the *Sample* exhibits maxima only at the same wavelengths as those of a similar preparation of the *Standard*.

- **B.**

Sample solution: Ignite 0.3 g of Methylparaben Sodium, cool, and dissolve the residue in about 3 mL of 3 N hydrochloric acid.

Acceptance criteria: A platinum wire dipped in the *Sample solution* imparts an intense, persistent yellow color to a nonluminous flame.

ASSAY

- **Procedure**

Mobile phase: Methanol and a 6.8 g/L solution of potassium dihydrogen phosphate (65:35, v/v)

System suitability solution: 5.0 µg/mL each of *p*-hydroxybenzoic acid and USP Methylparaben RS in *Mobile phase*

Standard solution: Dissolve 50.0 mg of USP Methylparaben RS in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Sample solution: Dissolve 50.0 mg of Methylparaben Sodium in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.3 mL/min

Injection volume: 10 µL

Run time: About 5 times the retention time of the methylparaben peak

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The retention time for methylparaben is about 2.2 min; the relative retention times for *p*-hydroxybenzoic acid and methylparaben are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the *p*-hydroxybenzoic acid and methylparaben peaks, *System suitability solution*

Relative standard deviation: NMT 0.85% for six injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methylparaben sodium ($C_8H_7NaO_3$) in the portion of Methylparaben Sodium taken:

$$\text{Result} = P \times (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2})$$

P = labeled purity of USP Methylparaben RS expressed as a percentage

r_U = peak area of methylparaben from the *Sample solution*

r_S = peak area of methylparaben from the *Standard solution*

C_S = concentration of methylparaben in the *Standard solution*

C_U = concentration of Methylparaben Sodium in the *Sample solution*

M_{r1} = molecular weight of methylparaben sodium, 174.13

M_{r2} = molecular weight of methylparaben, 152.15

Acceptance criteria: 95.0%–102.0% on the anhydrous basis

IMPURITIES

• **Related Compounds**

Mobile phase, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: Dilute 1.0 mL of the *Sample solution* with *Mobile phase* to 20.0 mL. Dilute 1.0 mL of this solution with *Mobile phase* to 10.0 mL.

System suitability

Sample: *System suitability solution*

[Note—The retention time for methylparaben is about 2.2 min; the relative retention times for *p*-hydroxybenzoic acid and methylparaben are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the *p*-hydroxybenzoic acid and methylparaben peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria

***p*-Hydroxybenzoic acid:** NMT 3.0%; the peak area in the *Sample solution*, multiplied by 1.4 to correct for the calculation of content, is NMT 6 times the area of the principal peak in the *Standard solution*.

Unspecified impurities: NMT 0.5%; the peak area of each impurity in the *Sample solution* is NMT the area of the principal peak in the *Standard solution*.

Total impurities: NMT 1.0%; the total peak area for all unspecified impurities in the *Sample solution* is NMT twice the area of the principal peak in the *Standard solution*.

• **Chloride and Sulfate,** *Chloride*⟨221⟩

Sample: 0.2 g

Control: 0.10 mL of 0.020 N hydrochloric acid

Acceptance criteria: 0.035%; the *Sample* shows no more chloride than the *Control*.

• **Chloride and Sulfate,** *Sulfate*⟨221⟩

Sample: 0.25 g

Control: 0.30 mL of 0.020 N sulfuric acid

Acceptance criteria: 0.12%; the *Sample* shows no more sulfate than the *Control*.

SPECIFIC TESTS

• **Completeness of Solution** ⟨641⟩

Sample solution: 1 g of Methylparaben Sodium dissolved in water

Acceptance criteria: Meets the requirements

- **pH** ⟨791⟩

  Sample solution: 1 mg/mL

  Acceptance criteria: 9.5–10.5

- **Water Determination,** *Method I* ⟨921⟩**:** NMT 5.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.

- **USP Reference Standards** ⟨11⟩

  USP Methylparaben RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METHYLPARABEN SODIUM	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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